

EXHIBIT G

Redesigning Liver Distribution to Reduce Variation in Access to Liver Transplantation

A Concept Paper from the OPTN/UNOS Liver and Intestinal Organ Transplantation Committee

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Executive Summary

There are significant geographic differences in access to liver transplantation across the United States. Where transplant candidates are listed affects how likely they are to receive a liver transplant and therefore their likelihood of death.

In 2013, 1,523 candidates (an average of eight per day) died while waiting for a liver transplant. Another 1,552 were removed from the waiting list because they were considered too ill to transplant. Candidates in some parts of the country must wait until they are very sick before they receive a liver transplant, while those in other parts of the country may receive transplants when they are much less ill.

The Organ Procurement and Transplantation Network (OPTN) is charged with developing a national transplant system that uses objective criteria, based on medical evidence, to provide all candidates nationwide with equitable access to transplantation. Where there are significant disparities, there is opportunity for improvement. Even so, many factors contribute to these disparities, and no single approach can equalize the experience of all candidates nationwide.

The OPTN manages the process of matching organs from deceased donors with medically compatible transplant candidates nationwide. For matching livers, the process involves two components:

- a ranking component for ordering candidates according to medical urgency (allocation)
- a pattern of geographic areas of the country where donated livers are matched to a priority-ranked list of candidates (distribution)

Liver **allocation** has been based on the model for end-stage liver disease (MELD) and pediatric end-stage liver disease (PELD) scores since 2002. This system prioritizes candidates based on the risk of death while awaiting liver transplantation. The MELD/PELD system has proven to be highly objective and a reliable predictor of most liver candidates' short-term risk of dying without receiving a transplant. While the MELD/PELD system has been adjusted since its implementation to meet more precise needs and conditions of certain groups of liver candidates, this concept document does not suggest any fundamental change to its use.

Liver **distribution** has been based historically on the geographic relationship between the hospital where the organ is recovered and the transplant hospital where the candidate is listed. Similar to kidney and pancreas allocation, the current liver distribution system uses a "local, regional, national" algorithm.

The local distribution unit is defined as the donation service area (DSA) of an organ procurement organization (OPO). There are 58 OPOs nationwide. Each serves a unique service area, which may range from a single large metropolitan area to multiple states. OPOs also vary widely in the number of people residing within their DSA, the frequency of deaths of people medically suitable to be organ donors, and the number of transplant centers and transplant candidates located within the DSA.

The OPTN system is divided into 11 geographic regions. The regional boundaries were based upon historic organ sharing relationships. While the regional structure was developed originally

to facilitate organ allocation and to provide individuals with the opportunity to discuss issues regarding organ procurement, allocation and transplantation that are unique to their particular geographic area, the regions were not designed for optimal organ distribution.

Addressing These Disparities

The Health Resources and Services Administration (HRSA) explicitly addressed fair access and geographic disparities in the OPTN final rule, effective March 2000. Additional recommendations by the Institute of Medicine and the U.S. Department of Health and Human Services' Advisory Committee on Transplantation support the need for effective distribution of livers based on medical evidence and not necessarily utilizing arbitrary DSA boundaries.

Over the years, the OPTN has enacted a series of changes to liver allocation and distribution policy to broaden urgent candidates' access to liver transplantation and minimize the effect of geography. These efforts collectively have reduced deaths among waiting list candidates, a key measure of system effectiveness. They have not, however, significantly reduced geographic variation in the level of medical urgency many candidates must reach to receive liver transplants.

In November 2012, the OPTN/UNOS Board of Directors agreed that geographic disparities in candidate access to liver transplants are unacceptably high. The Board charged organ specific committees, including the OPTN/UNOS Liver and Intestinal Organ Transplantation Committee, to develop policy to minimize the effects of geography on access to transplantation for listed candidates.

The Liver Committee has investigated a number of approaches to reduce geographic disparity, in order to select the approach that may result in the most effective gains, while minimizing undesirable effects such as increases in organ preservation time, costs related to organ preservation and transportation, and organ discards. A leading method under consideration, as an alternative to existing local/regional liver distribution, is distribution based on districts that were mathematically optimized to reduce the variation in the median MELD at transplant. Additionally, statistical and simulation modeling strongly suggests that using optimized geographical allocation districts would likely reduce both waitlist deaths and variation in the MELD or PELD scores at transplant. A series of maps have been generated using mathematical optimization techniques designed to decrease geographic disparity based upon criteria identified by the Liver Committee.

Summary of Results

The below table shows some summary results from the models being considered, as well as results for the current system, full regional sharing using the current 11 regions, and national sharing.¹ National sharing would represent the "outer edge" in terms of reducing the effects of geography for the sake of comparison, but is not under consideration. As compared to the current system, maps of 4 and 8 districts would reduce the disparity, as measured by the

¹ These are results of a 5-year simulation period using the Liver Simulated Allocation Model (LSAM). For more information about the LSAM, see the Appendix.

standard deviation of the MELD score at transplant across all the DSAs. Further, waiting list and total deaths would be greatly reduced.

Districts	Standard deviation, MELD @ transplant	% of Transplants with MELD scores	% of Transplants with MELD scores	% Pediatric	Net total deaths (over 5 years)	Net waitlist deaths
		<15	MELD >25			
4	1.87	2.5%	64.3%	8.7%	-553.8	-581.1
8	2.08	3.7%	59.6%	8.1%	-332.4	-342.1
Current System	3.01	5.8%	50.1%	7.5%	0	0
Regional	3.26	5.5%	54.3%	7.7%	-164.6	-122.4
National	1.66	1.9%	83.3%	10.4%	-343.6	-509.9

Potential Concerns

Any potential change to organ distribution will likely raise concerns and questions. The Liver Committee recognizes several areas of concern, including the potential for increased costs, organs being shifted from higher performing OPOs to lower performing OPOs under broader sharing, and potentially poorer post-transplant outcomes due to transplanting more critically ill candidates. Recent modeling analysis have included results related to total costs and organ import/export for the various alternatives discussed. These are described in detail in this document. In summary, the modeling suggests that total costs (pre-transplant, transport, transplant plus one year follow-up, and plus 3 years of follow-up) would decrease under redistricting due to the decrease in the cost of pre-transplant care. Further, there were no apparent relationships between OPO performance metrics and several metrics related to liver distribution.

Path Forward

After reviewing the modeling data, the Liver Committee unanimously agreed to seek public input on the concepts it has discussed.

It is important to note that this document is not a policy proposal. It is a concept document, intended to inform all interested parties about the status of the Liver Committee's discussion and seek valuable input, including alternative approaches, for further consideration. Any resulting proposal will be submitted for public comment to allow any interested party to share additional opinions, question or recommendations. The Liver Committee will consider and respond to those comments before any final proposal is submitted to the Board for consideration. **The earliest any potential policy proposal will be circulated for public comment is in the spring of 2015.**

We encourage all interested organizations and individuals to review the concepts and supporting information in this document, then provide responses to a brief questionnaire. These responses will be used to guide additional discussion at a public forum, to be held in September

2014 in Chicago. The Liver Committee is willing to consider any alternative concepts suggested and will use this input to assist in further development of liver policy to minimize the effects of geography on access to transplantation for listed candidates.

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Introduction

The OPTN/UNOS Liver and Intestinal Organ Transplantation Committee (the Liver Committee) requests feedback from the transplant community and the public regarding the next steps to consider as it seeks to reduce the variation in access to liver transplantation. This paper summarizes the challenges in fair access to liver transplants posed by geographic disparity, concepts under current consideration, and alternative approaches investigated. This concept paper also includes a link to a questionnaire. Feedback from that questionnaire will be used to

develop a forum for participants to further discuss the concepts in this paper and recommend ways to address the current inequities in access to liver transplantation.

42 CFR § 121.8

*Allocation of Organs
Allocation policies ... (8) shall not be based on
the candidate's place of residence or place of list*

Many factors affect the geographic variation in how ill candidates must be in order to have routine access to liver transplantation in the United States. The OPTN/UNOS Board of

Directors has directed the Liver Committee to address factors within the purview of the OPTN to provide more equal access to liver transplantation. The Liver Committee has investigated and implemented several attempts to address these inequities.

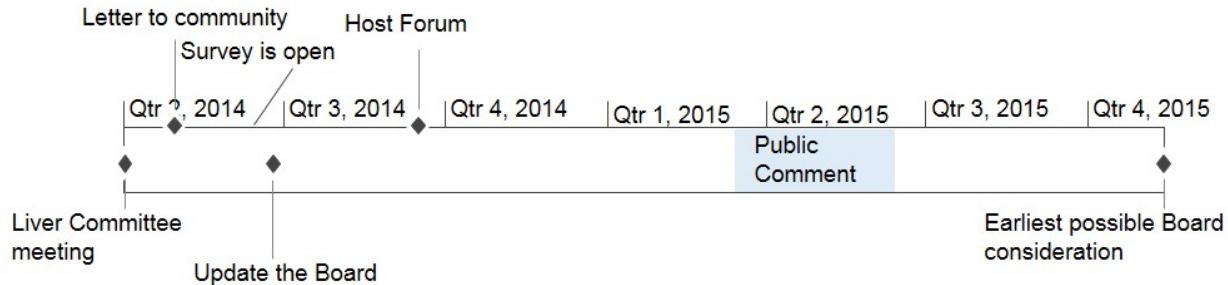
Since 2011, the Liver Committee has investigated redistricting as a possible solution to these geographical inequities.² Redistricting would involve drawing new geographic boundaries for liver distribution to be used instead of the current regions and DSAs. These new boundaries would be optimized to address the current inequities in access to liver transplantation. Like any large potential change, there are several questions raised by this potential solution. This paper attempts to identify and provide information about these questions.

We encourage any interested organizations and individuals to review the concepts and supporting information in this document, and then provide responses to a brief questionnaire. These responses will be used to guide additional discussion at a public forum, to be held in September 2014 in Chicago. The Liver Committee is willing to consider any alternative concepts suggested, and it will use this input to assist in further development of liver policy to

Reduce the variation in access to liver transplants for candidates nationwide.

It is important to note that this document is *not* a policy proposal. It is a concept document, intended to inform all interested parties about the status of the Liver Committee's discussion and seek valuable input, including alternative approaches, for further consideration. Any resulting proposal will be submitted for public comment to seek additional opinions, questions or recommendations. The Liver Committee will consider and respond to those comments before any final proposal is submitted to the Board for consideration. **The earliest any potential policy proposal will be circulated for public comment is in the spring of 2015.**

² Summary of OPTN/UNOS Liver and Intestinal Organ Transplantation Committee Meeting (December 14, 2011). Available via:
http://optn.transplant.hrsa.gov/CommitteeReports/interim_main_Liver&IntestinalOrganTransplantationCommittee_1_1_1_2012_9_45.pdf



The Current System

OPTN membership is divided into 11 geographic regions, each of which contains multiple Organ Procurement Organizations (OPOs) with a unique donation service area (DSA). The regional structure was developed to facilitate organ allocation and to provide individuals with the opportunity to discuss issues regarding organ procurement, allocation and transplantation that are unique to their particular geographic area. The regional boundaries were established to recognize historic organ sharing relationships; however, the current regional boundaries were not designed to optimize liver distribution.

Liver allocation has been based on the model for end-stage liver disease (MELD) and pediatric end-stage liver disease (PELD) scores since 2002. This system prioritizes

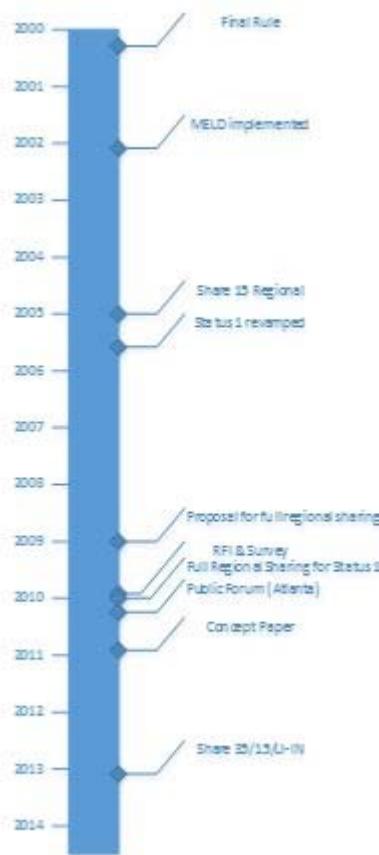
candidates based on the risk of death while awaiting liver transplantation. The MELD/PELD system has proven to be highly objective and a reliable predictor of most liver candidates' short-term risk of dying without receiving a transplant. While the MELD/PELD system has been adjusted since its implementation to meet more precise needs and conditions of certain groups of liver candidates, this concept document does not suggest any fundamental change to its use.

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INSTITUTE OF MEDICINE, 1999 RECOMMENDATION 1 Establish Organ Allocation Areas for Livers

The committee recommends that the DHHS final rule be implemented by the establishment of Organ Allocation Areas (OAAAs) for livers-each serving a population base of at least 9 million people (unless such an area would exceed the limits of acceptable cold ischemic time). OAAAs should generally be established through sharing arrangements among organ procurement organizations to avoid disrupting effective current procurement activities.

Concerns with Geographical Distribution



The Health Resources and Services Administration (HRSA) explicitly addressed fair access and geographic disparities in the OPTN final rule, effective March 2000.³ The final rule built upon findings of a 1999 study of the OPTN by the Institute of Medicine (IOM).⁴ The IOM's leading recommendation was the establishment of liver allocation areas broad enough to provide for medically effective distribution of organs. Further recommendations by the HHS Advisory Committee on Transplantation (ACOT) in 2010 approved a recommendation that states organ allocation should be evidence-based and not based on the arbitrary boundaries of OPOs or their DSAs.⁵ HRSA supports effective approaches to develop distribution systems that minimize this variation.

ACOT Recommendation 51

The ACOT recommends that the Secretary take steps to ensure the OPTN develops evidence-based allocation policies which are not determined by arbitrary administrative boundaries such as OPO service areas, OPTN regions and state boundaries.

The current efforts are a continuation this multi-year effort by the OPTN and the Liver Committee to address these geographical inequities. Some of these attempts have been in place for several years, some were only recently implemented, and others were never implemented. These attempts include:

³ 42 CFR Part 121, see http://optn.transplant.hrsa.gov/policiesAndBylaws/final_rule.asp, hereafter referred to as the "final rule." (§ 121.8(b) Allocation performance goals. Allocation policies shall be designed to achieve equitable allocation of organs among patients consistent with paragraph (a) of this section through the following performance goals:

...
 (3) Distributing organs over as broad a geographic area as feasible under paragraphs (a)(1)-(5) of this section, and in order of decreasing medical urgency
 ...
 (8) Shall not be based on the candidate's place of residence or place of listing, except to the extent required by paragraphs (a)(1)-(5) of this section.)

⁴ 64 FR 56658 (Oct. 20, 1999). Institute of Medicine. Organ Procurement and Transplantation: Assessing Current Policies and the Potential Impact of the DHHS Final Rule. Washington, DC: The National Academies Press, 1999.

⁵ Minutes of August 19, 2010 meeting of the Advisory Committee on Organ Transplantation. Available via: <http://organdonor.gov/legislation/acotrecs51.html>.

- Share 15 Regional
- Full Regional Sharing
- Concentric Circles
- Share 15 National
- Share 35 Regional⁶

Analysis of the Current System

Candidates in some parts of the country must wait until they are quite ill before they receive a liver transplant, while those in other areas receive transplants when they are much less ill. A study by Massie and Segev published in the American Journal of Transplantation in 2011 demonstrated the wide variation in *rates of transplant* across the DSAs. Figures 1 and 2 below illustrate these disparities.

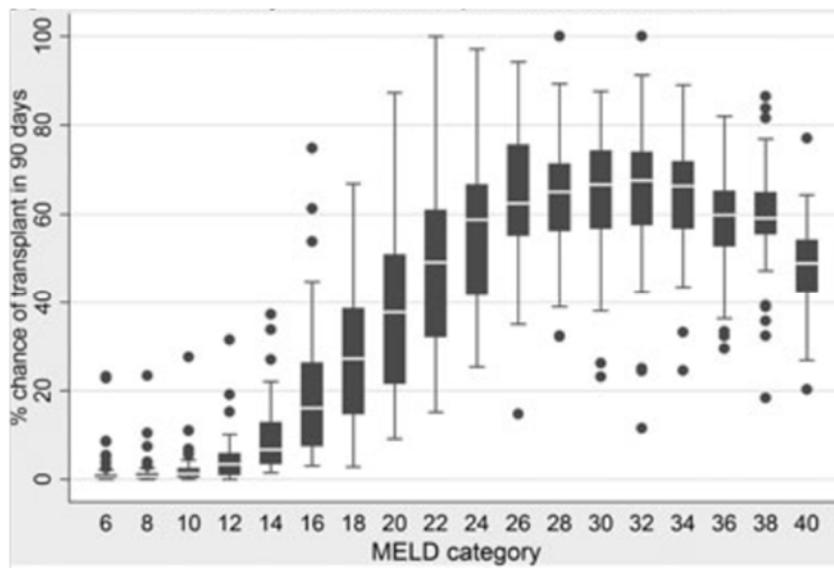
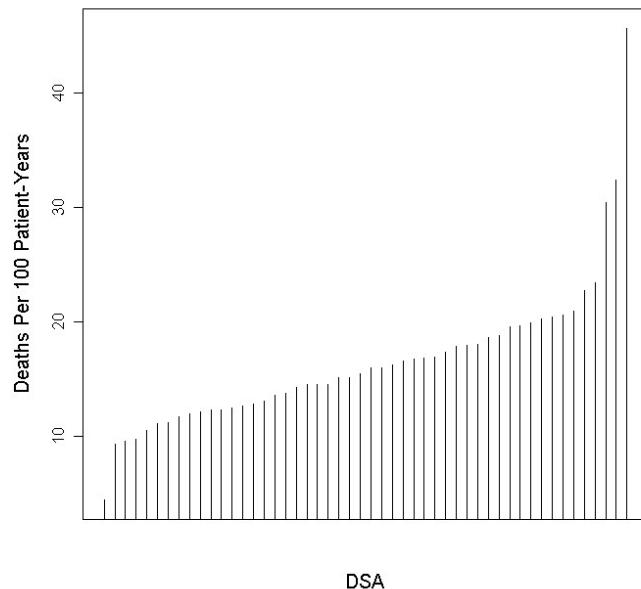


Figure 1: 90-day Rate of Transplant across DSAs⁷

Figure 1 illustrates this disparity by showing the wide variation in rates of transplant across the 58 OPOs. For example, a candidate with a MELD score of 38 might have an 18% chance of transplant in one OPO, versus an 86% chance in another.

⁶ See the appendix for more information about these previous efforts.

⁷ Massie, A. B., Caffo, B., Gentry, S. E., Hall, E. C., Axelrod, D. A., Lentine, K. L., Schnitzler, M. A., Gheorghian, A., Salvalaggio, P. R. and Segev, D. L. (2011), *MELD Exceptions and Rates of Waiting List Outcomes*. American Journal of Transplantation, 11: 2362–2371. doi: 10.1111/j.1600-6143.2011.03735.x



DSA

Figure 2: Death Rate per 100 Patient-Years on Waitlist by DSA, 2011

Figure 2 illustrates the wide variation in death rates across the DSAs. Another way to view these disparities is by looking at the variation in the median MELD at transplant, as shown in Figure 3.

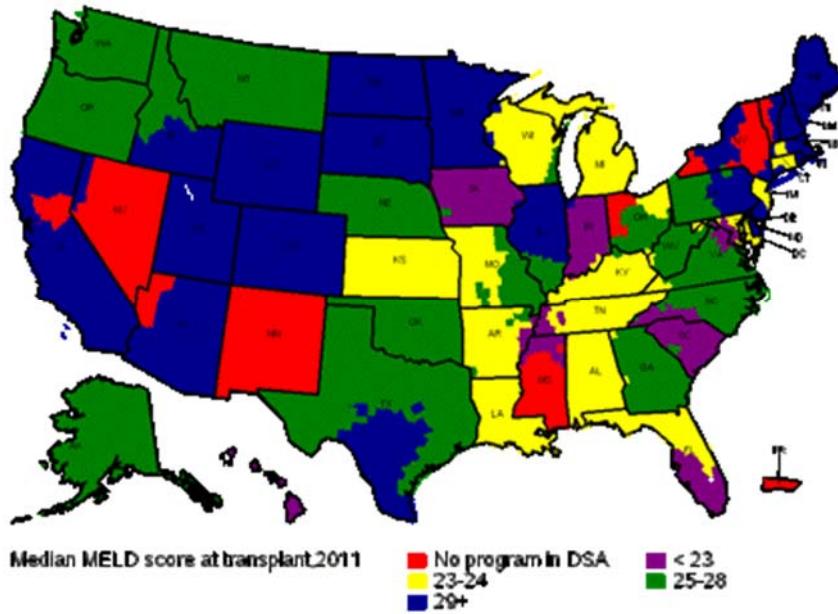


Figure 3: Median MELD score at Transplant, 2011

The Liver Committee is also aware of the differences that exist in utilization, as illustrated by Figure 4. The degree to which the number of livers transplanted is different from the number expected based on statistical analysis of donor characteristics varies across the country.

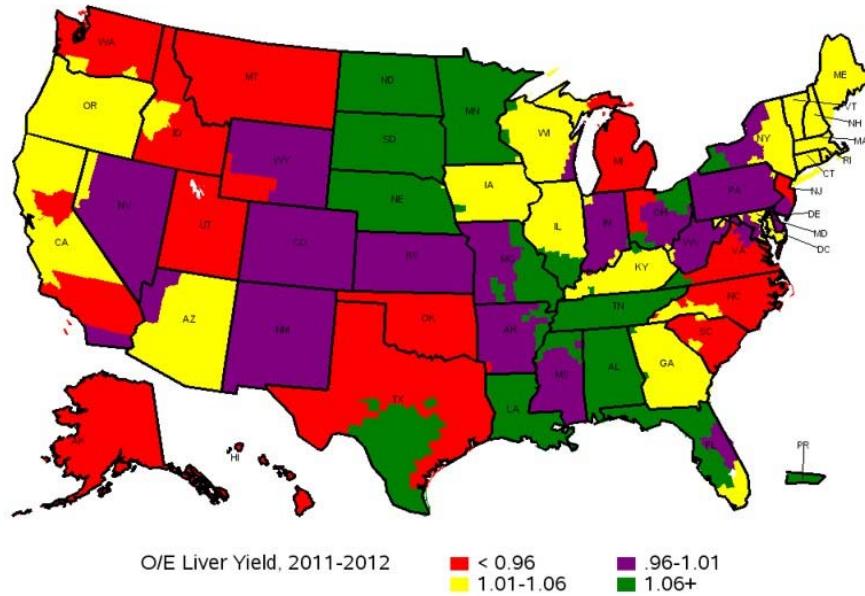


Figure 4: Observed to Expected Liver Yield, 2011-2012

Where these variations exist, improvements can be made to increase care and access for candidates. The OPTN has prioritized reducing the degree to which OPTN policies contribute to these disparities. While this has been a key goal of the organization, it is a very complex problem and may be addressed by different organ systems in different ways. These issues are not new and there have been many attempts at addressing them over the years.

Redistricting as a Potential Solution

Redistricting is an established area of operations research that has most notably been applied to designing voting and school districts. Application of this to liver distribution originated under an NIH Challenge Grant to explore optimization methods in the context of organ allocation. At the 2011 American Transplant Congress, Sommer Gentry, Ph.D., presented this study exploring optimization methods in the context of organ allocation. The Scientific Registry of Transplant Recipients (SRTR) has applied this concept to design optimized districts for liver distribution. The mathematics behind optimization has been described in great detail in the published literature.⁸

The next year, in June 2012, the OPTN/UNOS Board of Directors adopted an OPTN Strategic Plan that included reducing geographic disparities in access to transplantation as one of its objectives.⁹ The plan called for an examination of the effectiveness of the existing regional boundaries and consideration of new methods for organ distribution.

⁸ Gentry, S. E., Massie, A. B., Cheek, S. W., Lentine, K. L., Chow, E. H., Wickliffe, C. E., Dzebashevili, N., Salvalaggio, P. R., Schnitzler, M. A., Axelrod, D. A. and Segev, D. L. (2013), *Addressing Geographic Disparities in Liver Transplantation Through Redistricting*. American Journal of Transplantation, 13: 2052–2058. doi: 10.1111/ajt.12301

⁹ OPTN Strategic Plan Available via: http://optn.transplant.hrsa.gov/ContentDocuments/OPTN_Strategic_Plan.pdf.

In November 2012, the OPTN/UNOS Board of Directors agreed that the observed geographic disparities in transplant candidate access to organ offers were unacceptably high. To begin analyzing redistricting as a possible solution to the geographic disparities, the Board charged organ-specific committees, including the Liver Committee, to develop policy to minimize the effects of geography on access to transplantation for listed candidates. While the organ specific committees focused on defining a metric of fairness for their specific organ system, the Policy Oversight Committee (POC), comprised of the vice-chairs from the other OPTN/UNOS committees, was tasked with developing general principles to consider when addressing observed geographic disparity in candidate access to transplants.

Cross-Organ, System-Wide Issues

In September and October 2013, the POC discussed the efforts of the organ-specific committees to redraw their organ distribution regions. The Liver Committee came to several conclusions where there was general agreement:

- Distribution should not begin at the local level but should, instead, begin at least at the broader regional level.
- Regions for organ distribution should be relatively contiguous.
- DSA and regional boundaries were not necessarily appropriate for defining organ distribution areas, and individual organ-specific committees should be able to revise such distribution areas as needed to achieve the overall goals of OPTN policy.
- Different regions could exist for distribution and for other administrative purposes.¹⁰ The use of zones in thoracic allocation had already started this decoupling. Each organ should have its own metrics for measuring and monitoring the degree of geographic variation in fair access for transplant candidates.
- Metrics other than equity or fairness, such as utility and efficiency, should also be considered in any system change.
- All metrics should measure the impact on vulnerable populations such as children, the elderly, ethnic minorities, and highly-sensitized candidates.
- Each organ-specific committees should determine the makeup of its own review boards and decide whether to have a national review board, follow the administrative regions, or follow the allocation regions acknowledging it is more important to have consistency within the organ system than across organ systems.

Considerations of Liver Committee

In response to the final rule's performance mandates, ACOT's recommendation, the transplant community's ongoing feedback, the POC's recommendations, and the Board's directive, the Liver Committee considered what improvements in the distribution of livers would be feasible in terms of logistics, costs and risks related to transportation, recipient outcomes, and community acceptance.

¹⁰ As mentioned earlier, regions are used for multiple purposes (committee representation, review boards, in-person member meetings, allocation, etc.).

To address the Board's direction define a disparity metric for liver distribution; the Liver Committee selected the variance in the median MELD score at transplant across DSAs, as MELD has been shown to accurately reflect (with few exceptions) a candidate's severity of illness.¹¹

The Liver Committee agreed upon the following parameters for these optimized maps:

- The number of districts should be at least 4 and no more than 8;
- The minimum number of transplant centers per district is 6;
- The maximum median travel time between DSAs placed in the same district is 3 hours;
- The number of waitlist deaths under redistricting must not be statistically significantly higher than in the current system;
- The districts should be contiguous.

The Liver Committee investigated distribution based on fewer allocation districts as an alternative to the existing local/regional distribution. Using simulation modeling to predict how proposed changes to distribution may affect the transplant system, the SRTR designed optimal "districts," that, if utilized for liver distribution, would reduce the disparities that occur under the current system. Statistical modeling strongly suggests that using fewer geographical allocation districts would likely result in reduced waitlist deaths and a reduced variation in the MELD or PELD scores at transplant. These maps were generated by optimizing the areas to decrease disparity without increasing deaths.

Predicted Benefits of Liver Redistricting

The SRTR presented the results of several redistricting solutions with varying numbers of districts, compared to the current system: tiered sharing, full regional sharing, and national sharing. The level of disparity for redistricting, as measured by the standard deviation of MELD score at transplant across donation service areas (DSAs), would be markedly reduced with 8 districts, having 4 districts would further lower waitlist deaths over the 5-year simulation (n=554 total deaths over five years) as shown in Table 1. LSAM currently uses historic acceptance practices, which might have led to more discards than would occur under broader sharing. When Share 15 was implemented, acceptance practices appear to have changed such that some centers began accepting organs that they did not previously accept. Such behavioral changes are not included in the LSAM simulations.¹² Therefore, the estimates of the number of lives saved are probably conservative.

While the median transport time does not appear to change much across the options, the proportion of organs that would be expected to fly increased from 44% under the current system

¹¹ For discussion of other metrics discussed by the Committee, see the Minutes of OPTN/UNOS Liver and Intestinal Organ Transplantation Committee Meeting (January 24, 2013). Accessed via: http://optn.transplant.hrsa.gov/CommitteeReports/interim_main_Liver&IntestinalOrganTransplantationCommittee_2_27_2013_12_4.pdf.

¹² Pomfret, E. A., Fryer, J. P., Sima, C. S., Lake, J. R. and Merion, R. M. (2007), *Liver and Intestine Transplantation in the United States, 1996–2005*. American Journal of Transplantation, 7: 1376–1389. doi: 10.1111/j.1600-6143.2007.01782.x

to 64% and 74% with 8 and 4 districts, respectively.¹³ However, the transportation costs, as shown later, are a small component of the total costs.

Table 1: Results of Optimized Redistricting Plans (5-year LSAM Simulation)

Districts	Standard deviation, MELD @ Transplant	% of Transplants with MELD scores <15	% of Transplants with MELD scores MELD >25	% Pediatric	Net total deaths	Net waitlist deaths
4	1.87	2.5%	64.3%	8.7%	-553.8	-581.1
8	2.08	3.7%	59.6%	8.1%	-332.4	-342.1
Current System	3.01	5.8%	50.1%	7.5%	0	0
Regional	3.26	5.5%	54.3%	7.7%	-164.6	-122.4
National	1.66	1.9%	83.3%	10.4%	-343.6	-509.9

After reviewing the modeling data, the Liver Committee unanimously agreed to seek public input on the redistricting concepts it has discussed and circulate the conceptual maps of 4 and 8 districts. The maps, and their projected impacts, are provided in Figures 5-8.

¹³ See the Appendix for more information about the effects of the redistricting solutions on organ transportation.

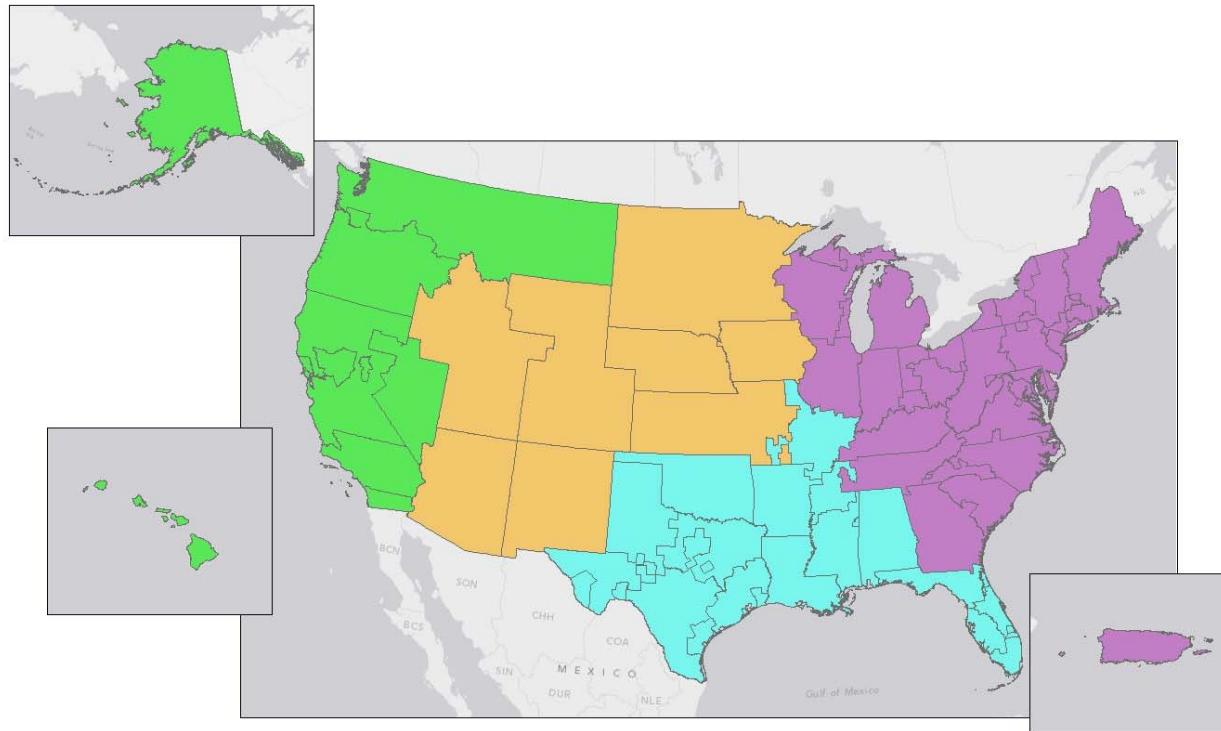


Figure 5: 4 district distribution model

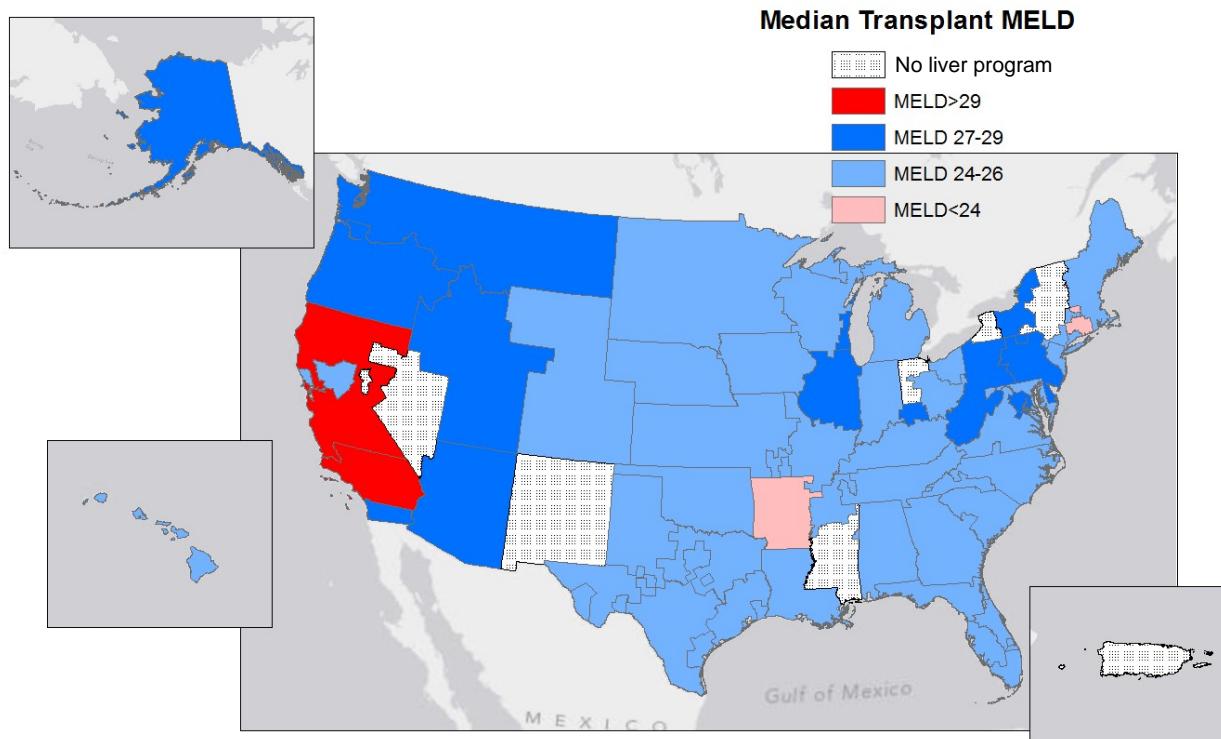


Figure 6: How 4 district distribution model reduces disparity

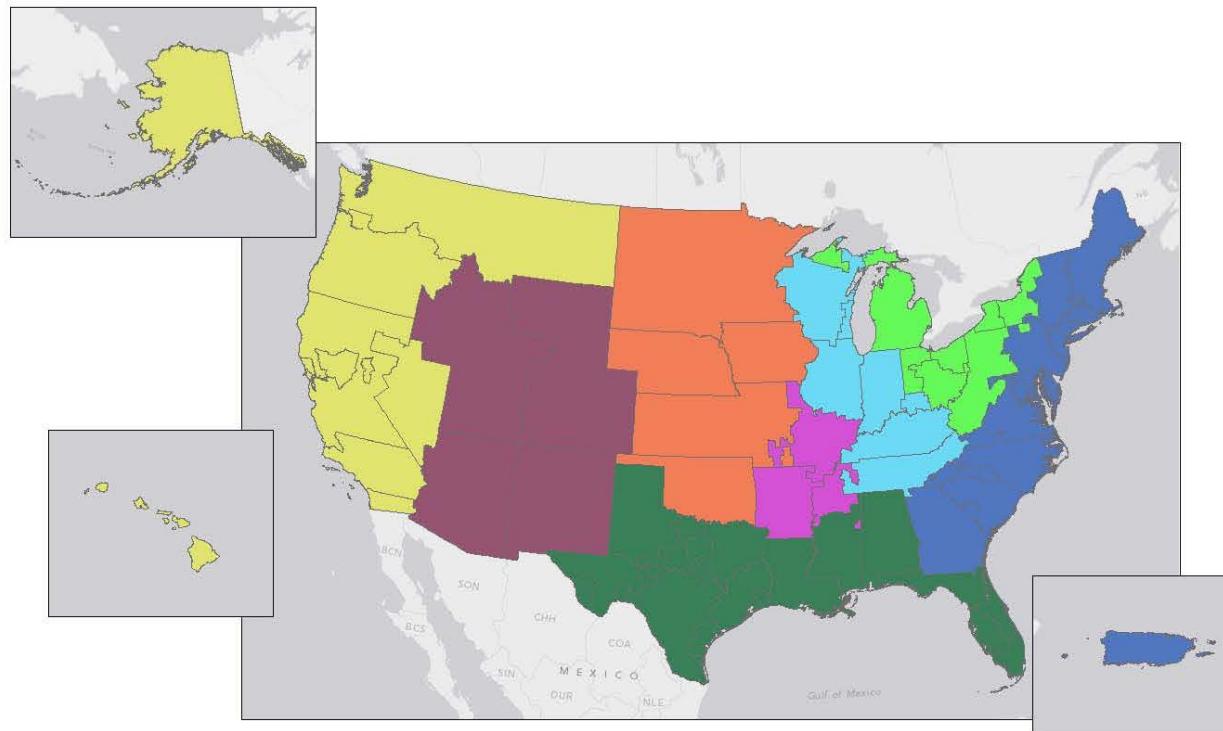


Figure 7: 8 district model

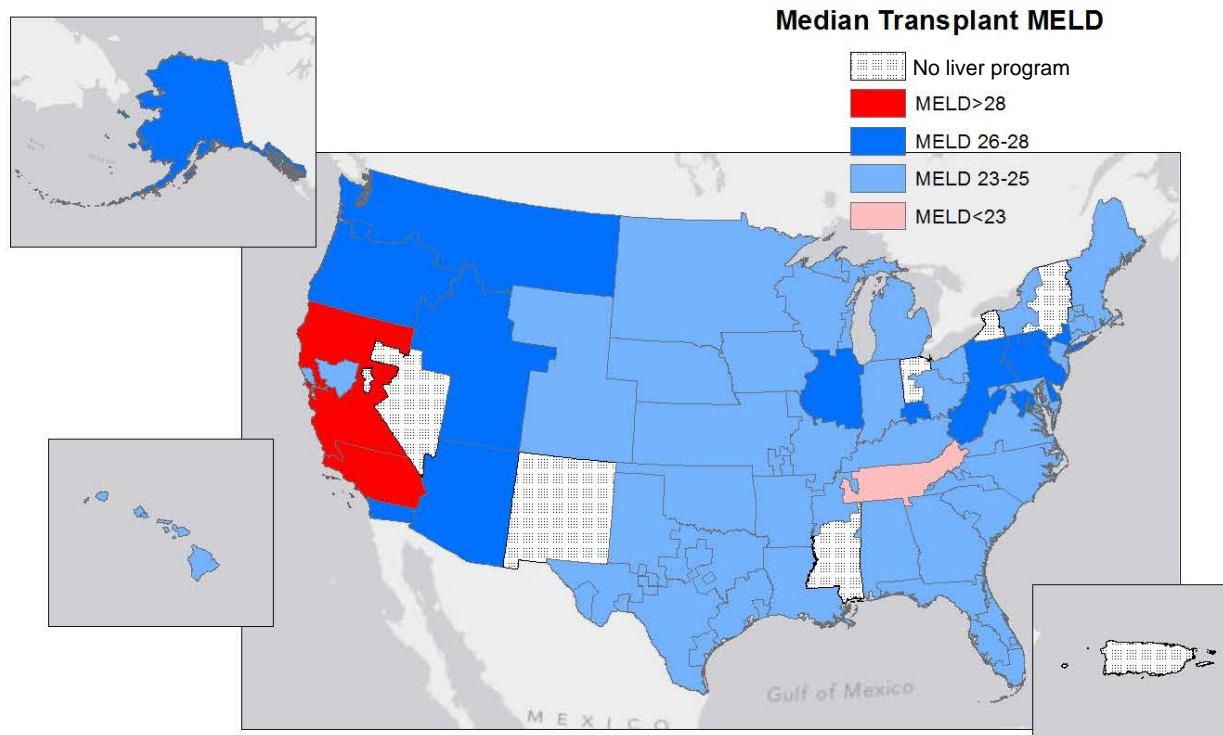


Figure 8: How 8 district model reduces disparity

Analyses of Potential Redistricting

The Liver Committee requested additional information about several aspects of any redistricting solution.

Areas of concern addressed by Liver Committee members include (1) information about costs, (2) the relationship between OPO performance and organ distribution (3) impact on donation rates, (4) relationship to transplant center volume, and (5) the impact of minority or disadvantaged populations. These data were provided for maps with 4 and 8 districts, as well as for the current policy, the previous policy, and full regional sharing using the current regions.

Financial Considerations

The Liver Committee has considered the potential costs of redistricting. The SRTR examined the total costs of transplant care: pre-transplant, transport, and transplant plus one year and 3 years of follow-up. This analysis was based upon two papers in addition to data provided by specific OPOs on the cost of charter flight information.¹⁴ With the exception of transportation costs, these are the costs to the payer (e.g., a private health insurance provider.)

The elimination of local as the first tier of allocation and the use of larger regions may increase the time, distances and frequency of travel for recovery teams, as well as the transportation cost at the center level. However, it is predicted to decrease the costs of pre-transplant care. These cost savings would be larger than the overall transportation cost increases. As a result, **total costs** (pre-transplant, transport, transplant plus one year follow-up, and transplant plus three years of follow-up) would decrease under redistricting due to the decrease in the cost of pre-transplant care.

Table 2: Costs shows these costs broken down by type of cost and possible options/solutions/models.

Table 2: Costs

Districts	Pre-Transplant Costs	Transportation Costs	Transplant Plus 1-year Follow up	2-3 year follow up	Total Costs
4	\$1,376,893,919	\$191,441,724	\$2,955,491,110	\$497,257,211	\$5,404,527,449
8	\$1,406,341,692	\$175,509,419	\$2,969,580,805	\$493,132,467	\$5,425,225,356

¹⁴ Salvalaggio, Paolo R., Nino Dzebisashvili, Kara E. MacLeod, Krista L. Lentine, Adrian Gheorghian, Mark A. Schnitzler, Samuel Hohmann, Dorry L. Segev, Sommer E. Gentry, and David A. Axelrod. "The interaction among donor characteristics, severity of liver disease, and the cost of liver transplantation." *Liver Transplantation*: 233-242. Salvalaggio, Paolo R., Paula Buchanan, Nino Dzebisashvili, Krista L. Lentine, David A. Axelrod, and Mark A. Schnitzler. "Liver transplantation cost in the model for end-stage liver disease era: Looking beyond the transplant admission." *Liver Transplantation*: 1270-1277.

Districts	Pre-Transplant Costs	Transportation Costs	Transplant Plus 1-year Follow up	2-3 year follow up	Total Costs
Current	\$1,651,204,930	\$124,863,503	\$2,988,449,895	\$485,889,231	\$5,650,506,926
Regional	\$1,507,658,537	\$165,351,072	\$2,977,351,064	\$491,003,037	\$5,518,322,216

Relationship to OPO Performance

Another issue considered is the relationship between OPO performance and the current geographical differences on access to transplantation for listed candidates

Some have commented that the current inequities are caused by poor OPO performance in those areas. The SRTR examined whether there is any relationship between OPO performance and liver distribution. They studied the observed/expected liver yield (O:E), whether the OPO was a net importer or exporter, and the median MELD at transplants. In the current system modeling, the SRTR found:¹⁵

In summary after extensive analyses, the following predictions were made:

- There is no apparent relationship between OPO performance metrics and liver import (using the current OPTN definition of organ yield), suggesting that the disparities are not caused by difference in OPO performance.
- Liver imports would flow to DSAs where eligible deaths are lower and where incident (new) listings are higher, with or without redistricting.
- With potential redistricting there was no difference in the rates of transplant by gender, but there was a statistically significantly higher number of pediatric candidates transplanted under the redistricting plans ($p<0.001$).

The SRTR then applied the same analysis to the potential redistricting plans and found:

- Under redistricting, there would still be no relationship between net import and O:E, and no relationship between net import and liver donor conversion rate.
- Centers in higher-yielding OPOs (higher O:E, higher conversion) would be expected to transplant at lower MELDs than those in poorer-performing OPOs under either redistricting plan. This represents a change from the current system under which there is no relationship between OPO performance and transplant MELD.

Impact on Donation Rates

Liver Committee members also asked what the impact of redistricting might be on organ donation. Concerns have been expressed that when organs are more broadly shared, local donation will decrease due to their community's sentiment for local use of organs. A survey

¹⁵ For the definition of "eligible death", see OPTN Policy 1.2 (Eligible Death) available via: http://optn.transplant.hrsa.gov/ContentDocuments/OPTN_Policies.pdf. Conversion rate is the percentage of times a death meeting eligible criteria (eligible death) becomes an actual donor.

conducted by HHS published in 2013 indicated that this is not the case.¹⁶ Eighty-two percent of survey respondents felt that organs should go to the most medically urgent patient regardless of their location in the United States.

Relationship to Transplant Center Volumes

Liver Committee members inquired about the possibility that redistricting may reduce transplant volumes at some centers, and perhaps result in center closures, especially in areas with currently low median MELD scores at transplant. Any changes to distribution will result in at least some change in specific transplant center volumes. The LSAM is designed to look at aggregate policy changes; it is not designed to be able to predict changes at specific programs. Further, behavioral changes, which cannot be predicted, may change acceptance practices as noted below; an increase in acceptance of livers may offset predicted decrease at the low volume centers.

Impact on Minority or Disadvantaged Populations

SRTR modeling analyses indicated that there would be no significant change in the percentage of transplants for blacks ($p=0.28$), or for “other” ethnicity ($p=0.08$) under the redistricting scenarios. The percent of transplanted candidates who are white would decrease ($p<0.001$) while the percent of transplanted candidates who are Hispanic would increase ($p=0.02$). The percentage of pediatric transplants increased slightly with either 8 or 4 districts as compared to the current system.

Additional Issues Requiring Further Analyses

Any policy change may have additional impacts beyond the primary goal(s) of the policy, both anticipated and unanticipated. A policy change may lead to behavioral changes that could not have been predicted using simulation modeling. As noted earlier, the implementation of Share 15 Regional in 2005 appeared to lead to changes in organ acceptance behavior. A study published in 2007 noted:

“Most interestingly, despite major changes in the MELD scores of recipients and marked reductions in the number of low-MELD transplants being performed after the implementation of the new policy, there was almost no change in the number of livers shared outside the local DSA under the new system. Specifically, there was no change in the proportion of locally transplanted or regionally transplanted livers. This suggests that the policy goals were realized through behavioral changes at the local level. Decisions at the local DSA level to accept donor livers for high-MELD candidates that

¹⁶ U.S. Department of Health and Human Services, Health Resources and Services Administration, Healthcare Systems Bureau, Division of Transplantation, *2012 National Survey of Organ Donation Attitudes and Behaviors*. Rockville, Maryland: U.S. Department of Health and Human Services, 2013. See also, generally, Gallup Organization. *The American public’s attitudes toward organ donation and transplantation*. Boston, MA: The Partnership for Organ Donation 1993. The Gallup Organization. *National Survey of Organ and Tissue Donation Attitudes and Behaviors*. U.S. Department of Health and Human Services, 2013.

would have previously been reserved for lower-MELD candidates (by turning down such offers for the higher-MELD candidates) may explain this phenomenon...¹⁷

Acceptance Practices

The implementation of Share 35 introduced some unanticipated issues and concerns related to sharing organs across regions. Centers and OPOs who had not previously worked together now needed to agree upon procurement and acceptance practices, often in the middle of the night or under difficult circumstances.

The Liver Committee has encouraged centers and OPOs to develop some clear “rules of engagement” to address these issues. These ongoing conversations and agreements would be crucial to the implementation of any of the redistricting plans, which remove the local tier from the distribution algorithm and would result in many more organs being shared outside the local area.

Review Boards

As mentioned above, regions are used for purposes beyond allocation. Changing the number and boundaries of regions for liver distribution does not require changes to how regions are used for in-person member meetings, committee representation, or member voting issues. However, it would have impacts on liver review board operations.

Review of MELD/PELD exception cases is currently handled by each of the 11 Regional Review Boards, a system that does not promote consistent reviews of the MELD/PELD scores across the U.S. A potential change to districts would likely require some other mechanism for review. The Liver Committee will have three broad choices to investigate and develop further:

1. Maintain the current regional review board structure. The heart review boards utilize the common 11 regions even though heart allocation does not utilize the same 11 regions.
2. Change to a national review board. Lung transplant exceptions are reviewed by a national board. In November 2013, the Board of Directors also charged the Liver Committee to develop a plan, to include a conceptual basis and a proposed timeline, for implementation of a National Review Board (NRB) for review of MELD/PELD exception applications. The Board requested that this be presented in June 2014, with a possible policy proposal ready for fall 2014 public comment.¹⁸
3. Change the makeup of the review boards to utilize the new districts. This would change the makeup and number of the review boards.

Multi-Organ Considerations

Finally, any change to the current boundaries for liver distribution would also require clear policies for multi-organ transplantation. For example, the Share 35 policy highlighted some confusion about the rules for sharing kidneys along with livers. The regional priority for

¹⁷ Pomfret, E. A., Fryer, J. P., Sima, C. S., Lake, J. R. and Merion, R. M. (2007), Liver and Intestine Transplantation in the United States, 1996–2005. *American Journal of Transplantation*, 7: 1376–1389. doi: 10.1111/j.1600-6143.2007.01782.x

¹⁸ For more information about a national liver review board, see the Appendix.

candidates with MELD scores of 35 and higher, some of whom have scores in the 35 to 40 range due to their need for dialysis, has led to more regional offers to those awaiting a combined liver-kidney transplant. Some areas of the country have agreed to share the kidney with the liver when the liver is accepted outside the local area. In other areas, there are no stated agreements. Going forward, these types of decisions will need to be addressed either by national policy or by agreements made by all the parties in the sharing area.

If a new distribution system is developed for liver transplantation while other organs continue to use the traditional 11 regions for distribution, policies should be developed that clearly describe how the allocation of multi-organ transplants should proceed.

Information Requested

Please review the information in this document and provide responses to the questionnaire by July 11, 2014. We welcome responses from individuals as well as institutions, and from any perspective or experience that may provide information to the Liver Committee. The Liver Committee also welcomes new and constructive alternative distribution concepts for consideration and has provided a response field for these suggestions within the questionnaire.

[Click here to give us your feedback.](#)

At a public forum to be held in September 2014, summary responses to the questionnaire will be displayed. In preparation for that forum, questionnaire responses will be used to determine the topics to be discussed.

Responses received after July 11, 2014 will be accepted and shared with the Liver Committee, but, if received after the cut off, may not be tallied in the summary of information prepared for the public forum. The forum will provide an additional opportunity for public input, as will the public comment period that follows the development of any resulting policy proposal.

We thank you and rely on your experience and perspective to help us best meet the needs of all transplant candidates

Appendices

Simulation Modeling

Potential changes to liver allocation were evaluated using the Liver Simulated Allocation Model (LSAM), a validated discrete event simulator that estimates outcomes under any specified liver allocation policy. The OPTN has been using LSAM for both research and policy development for over 10 years. The following scenarios were tested using LSAM:

- The current allocation policy
- Full regional sharing (no local tier) using the current regions; and
- Full “district” sharing (no local tier) with DSAs grouped into optimized areas of 4, 5, 6, 7, 8 and 11 districts, according to the outcomes of the model described above
- Concentric circles of 500 miles
- Full national sharing

LSAM uses historical inputs (e.g., donors and candidates, organ offer acceptance practices, removals for death or other reasons). An elaborate transport model was also developed to determine transport times. Transport distances were calculated from each donor hospital to each transplant center, and between centers and nearby airports. Drive times were calculated by Google’s driving algorithm. Flight segment lengths were estimated using scheduled departure and arrival times, per aircraft category (jet or turboprop). The transport time between every donor hospital and every transplant center was then estimated based on the most likely transportation mode, which was determined following extensive discussions and validation with two large OPOs.

LSAM produced numerous outputs, by DSA and region, for each allocation scenario, such as:

- Median MELD score at transplant (including the variance and range across DSAs)
- Number and rate of waitlist deaths
- Total deaths
- Percentage of livers allocated locally
- Percentage of livers allocated by transport mode (driving vs. flying)
- Average transport distance and time
- Percentage of transplants by various demographics (age, gender, ethnicity)
- Percentage livers to candidates with MELD scores >25

In March 2013, the Liver Committee reviewed data comparing several potential maps for distribution, including those using both contiguous (i.e., DSAs in each district must be geographically contiguous) and non-contiguous configurations, as well as the current system, full regional sharing using the current 11 regions, 500-mile concentric circles as the initial distribution unit, and national sharing. The Committee reviewed six optimized maps (A-F):¹⁹

¹⁹ For more information, see Minutes of the OPTN/UNOS Liver and Intestinal Organ Transplantation Committee Meeting (March 13, 2013). Accessed via: http://optn.transplant.hrsa.gov/CommitteeReports/interim_main_Liver&IntestinalOrganTransplantationCommittee_4_12_2013_14_17.pdf.

- A. 10 regions, non-contiguous DSAs
- B. 11 regions, non-contiguous DSAs
- C. 11 regions, contiguous DSAs
- D. 4 regions, non-contiguous DSAs
- E. 4 regions, contiguous DSAs
- F. 6 regions, contiguous DSAs

These results are shown in Table 3, and were based on 1-year LSAM modeling runs.

Table 3 Modeling Results Presented to the Liver Committee in March 2013

Map	Std. Dev. of the MELD @ Transplant	Std. Dev. in Waitlist Deaths	% MELD>25	Net Total deaths	Net Waitlist deaths	Median distance	Median time	% flying
A	3.02	5.23	64%	-85	-80	163	1.7	62%
B	2.51	5.55	62%	71	71	139	1.7	62%
C	2.72	5.61	66%	13	36	169	1.7	67%
D	2.78	4.96	71%	-164	-157	296	2.0	74%
E	2.84	4.87	72%	-153	-149	274	2.0	75%
F	2.81	5.18	67%	-97	-90	204	1.9	70%
Concentric Circles	3.1	5.27	62%	46	33	140	1.7	63%
Current	3.41	5.75	53%	0	0	68	1.5	44%
Regional	3.78	4.88	58%	-57	-63	137	1.7	61%
National	1.77	5.06	89%	-221	-202	768	2.9	89%

Based on these analyses, the SRTR concluded that, for concentric circles:

- The standard deviation of median MELD was 3.1, higher than in the optimized 11-region maps;
- Travel time (1.7 hours) and the percent flying (63%) was almost identical to 11-region maps;
- Net Waitlist deaths (46) were similar to the higher rates among optimized 11-region maps;
- Concentric circles were not superior to optimized 11-region maps on any metric.

Circles based on some fixed difference are not designed to optimize liver distribution as the optimized maps are designed to do. However, the Liver Committee understands that there may still be interest in seeing updated, 5-year LSAM results for concentric circles for comparison with the results for the 4- and 8- district maps. These analyses are currently underway.

In April 2014, the Liver Committee updated data for potential maps for distribution.²⁰ The results are an average of ten 5-year LSAM runs. Tables 4 and 5 provide summary statistics for each of the scenarios modeled.

Table 4: Projected Organ Transport Impacts

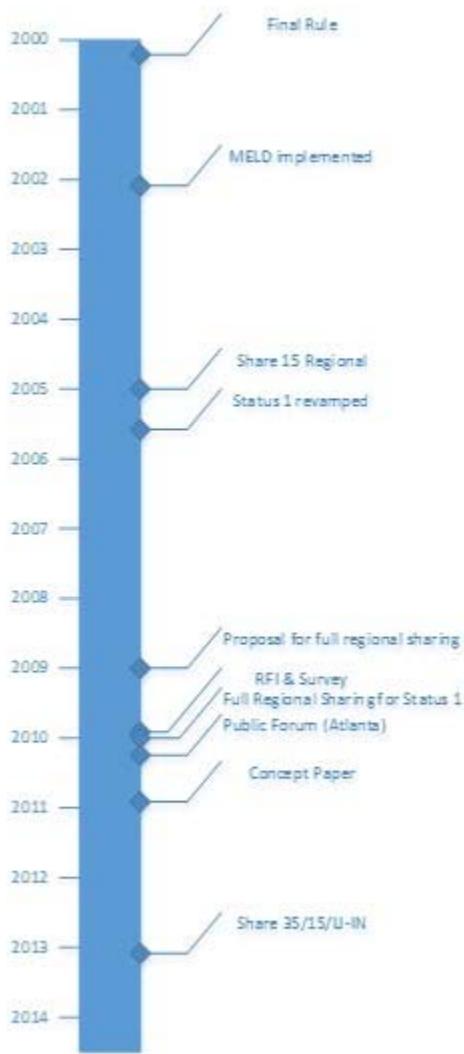
Districts	% Local	% District	% National	Median distance	Median hours transport	% flying
4	26%	73%	1%	340	2.05	74%
5	31%	67%	2%	354	1.91	73%
6	34%	64%	2%	232	1.85	70%
7	38%	60%	2%	192	1.78	66%
8	40%	58%	2%	178	1.75	64%
11	49%	48%	3%	143	1.71	62%
Current	73%	23%	4%	68	1.5	44%
Regional	49%	48%	4%	137	1.7	61%
National	18%	15%	67%	768	2.9	89%

Table 5: Projected Redistricting Impacts

Districts	Standard deviation of transplant MELD	% MELD <15	% MELD >25	Median transplant MELD	Net total deaths	Net waitlist deaths
4	1.87	2.5%	64.3%	26	-553.8	-581.1
5	2.01	2.9%	61.5%	26	-468	-441.8
6	2.01	3.2%	60.6%	26	-421.3	-431.7
7	2.04	3.5%	59.5%	25	-373.5	-382.2
8	2.08	3.7%	59.6%	25	-332.4	-342.1
11	2.44	4.5%	56.1%	25	-210.5	-239.7
Current	3.01	5.8%	50.1%	25	0	0
Regional	3.26	5.5%	54.2%	25	-164.6	-122.4
National	1.66	1.9%	83.3%	29	-343.6	-509.9

²⁰ See Minutes of the OPTN/UNOS Liver and Intestinal Organ Transplantation Committee Meeting (April 1, 2014). Accessed via: http://optn.transplant.hrsa.gov/CommitteeReports/interim_main_Liver&IntestinalOrganTransplantationCommittee_5_1_2014_11_31.pdf.

Previous Efforts to Reduce Variation in Access



The current efforts are a continuation of a multi-year effort by the Liver Committee to address these geographical inequities. Some of these attempts have been in place for several years, some were only recently implemented, and others were never implemented. Below are some previous attempts by the Liver Committee to address these geographical inequities.

Share 15 Regional

The Share 15 Regional policy, implemented in 2005, was intended to reduce waiting list deaths by directing livers to the candidates who would most benefit. Analysis of national data showed that the vast majority of candidates with a MELD/PELD score below 15 did not receive a net survival benefit from a liver transplant as compared to not receiving a transplant. Thus, the goal of the Share 15 Regional policy was to redirect deceased donor livers to more ill candidates and away from less ill candidates (MELD or PELD score < 15) who, in general, will live longer without a transplant than candidates with a higher MELD or PELD score. This goal has been met with no adverse impact on post-transplant outcomes.

Full Regional Sharing

Two separate proposals for full regional distribution of livers to all candidates ranked by their MELD or PELD score were distributed for public comment in the spring of 2009.²¹ The first proposal was to create a Regional-National allocation of livers for

the very sickest candidates, Status 1. The second proposed to eliminate local from the adult allocation algorithm entirely making regional the first level of allocation for all MELD/PELD candidates.

Based on public comment response, the Liver Committee withdrew the proposal to eliminate local allocation from consideration and did not forward it to the Board. The Board approved the proposal for Regional-National Sharing for Status 1, which was implemented in late 2010. However, as a result of the community's mixed feedback on the proposal for full regional

²¹ See Proposal to Create Regional Distribution of livers for MELD/PELD candidates, available via: http://optn.transplant.hrsa.gov/PublicComment/pubcommentPropSub_239.pdf and Proposal to Create Regional Distribution of livers for Status 1 liver candidates, available via: http://optn.transplant.hrsa.gov/PublicComment/pubcommentPropSub_238.pdf.

sharing for liver candidates, a number of requests and ideas were put forward for the Liver Committee to evaluate and assess in regards to improving the system.

[Concentric Circles](#)

Distribution via concentric circles, akin to the current thoracic organ distribution system, was also evaluated. (Under a concentric circle approach, distribution proceeds within a set of geographic intervals radiating outward from the location of the donor hospital, such as a radius of 500 miles, 1000 miles, etc.) Circles defined by population density were also considered. Although the use of concentric circles has many positive aspects, such as eliminating arbitrary geographic boundaries, distribution based on donor location rather than the transplant center, and current use and acceptance by the thoracic organ community, this system would substantially change liver distribution and may not be “feasible” given the current sentiments.

[Recent Changes to Liver Distribution Policy](#)

From 2009-2010 the Liver Committee sponsored multiple opportunities for community participation and feedback, including a Request for Information (RFI) document, questionnaires, and a public forum. These initiatives revealed several areas of common ground and the potential for consensus-building moving forward.

Expansion of the Share 15 Regional policy to a Share 15 National system received substantial support. Other concepts for distribution systems were studied in detail including some form of tiered regional distribution, whereby livers are first offered regionally to candidates with scores over a certain MELD or PELD threshold. Models of tiered sharing with thresholds of 35, 32, 29, 25 and 22 were studied and presented, with the higher thresholds receiving the greatest support. This concept ultimately led to the development of the policy proposal for Share 35 Regional.

Based on the feedback received through the RFI, questionnaire and public forum, a Concept Paper and questionnaire were distributed to the community in December 2010. The Liver Committee reviewed these results in February and March of 2011. Three-quarters of the respondents supported a Share 15 National policy. Similarly, the majority supported broader regional sharing at higher MELD scores. Finally, 72% of respondents supported some form of regional sharing.

Released for public comment in September 2011, the Liver Committee proposed an extension of the Share 15 Regional policy. Under this policy, deceased donor livers (for donors age 18 and higher) would be offered to all status 1A and 1B candidates and those with MELD or PELD scores of 15 or greater locally, regionally, and nationally before being offered to candidates with lower MELD or PELD scores. The Liver Committee also released a second, separate proposal for regional distribution of livers to candidates with MELD or PELD scores of 35 and greater.

[Ongoing Evaluation of Share 15 National, Share 35 Regional, and Liver-Intestine National Share](#)

The Liver Committee presented the Share 15 National and the Share 35 Regional policy proposals to the Board in June 2012, both of which were approved and implemented along with the Liver-Intestine National Share by UNOS on June 18, 2013. The Liver Committee has since been tracking the early impacts of these policies and will continue to do so.

The national data results at six months reveal the following:

- As predicted, the percentage of liver transplants for those with MELD scores of 35 or higher increased from 19.9% of total to 25.2%
- Overall deaths on the waiting list have decreased by 7% when compared to the six months prior to implementation ($RR^*=0.93$ [0.86, 1.0]).
- Regional sharing has increased, from 19.4% to 30.7%.
- While concerns had been expressed that cold ischemia time (CIT) and the distance the organs travel would increase with this policy change, this has not been demonstrated in the data at a national level.
- The percentage of discards has decreased nationally from 10.5% to 8.9%. While most regions have experienced a reduction in discards (defined as a liver recovered for transplant but not transplanted) in the six months following Share 35, two regions have experienced a higher number of organs discarded.
- The percentage of livers not recovered for transplant has remained the same at 13% of donors.

While Share 15 National, Share 35, and the Liver-Intestine National Sharing appear to be achieving the intended goals, regional variation persists in access to transplants for those candidates most at risk of dying. The Liver Committee will continue to monitor the effects of these policies, including patient and graft outcomes compared to the pre-Share 35 era, to address concerns regarding the best use of donated organs.

National Liver Review Board

In response to the November 2013 directive from the Board, the Liver Committee renewed discussions regarding a national liver review board.²² The Liver Committee reviewed MELD/PELD exception data from 2013 to assess the potential caseload. In 2013, there were approximately 7,200 cases submitted to the RRBs, including initial applications, appeals, and extensions. The addition of sodium to the MELD score is anticipated to eliminate the 1,200 fluid/sodium-related exception requests. If those exceptions currently included in policy (e.g., Cholangiocarcinoma, familial amyloidosis, etc.) are programmed into UNetSM, plus those for NET, PCLD, and PSC, the total could be reduced to just over 4,000 cases per year. (See Figure 9.) Advantages of a national liver review board may include:

- More consistent exception scores
- Potentially faster turnaround time for exceptions
- More ability to equalize workloads of review board members

Difficulties with a national liver review board may include:

- Application of regional agreements will make national standards more complicated
- Current regional disparities in MELD at transplant impact the average MELD requested and approved by review boards
- This may increase the workload for those review board members coming from regions that do not currently have a high level of exceptions

7200	current cases
<u>-1200</u>	(if MELD-Na approved)
6000	
<u>-1000</u>	(if specific criteria accepted for NET/PCLD/PSC are programmed)
5000	
<u>- 860</u>	(if other exceptions are programmed)
4140	cases/year

Figure 9: Assessment of Potential Caseload under a National Liver Review Board

²² The Committee previously circulated a proposal for a national liver review board in 2004. The proposal did not have broad support amongst the regions, would have been costly to implement, was not forwarded to the Board for approval, and therefore was not implemented.

Contents of Questionnaire

Please consider the concepts and evidence described in the Concept Document and then indicate the degree of your support or disagreement with the questions below.

Only items marked with an asterisk (*) are required.

1. *The ability of all liver transplant candidates to receive timely access to liver transplantation is a component of a fair national organ transplant system.
 Strongly Agree
 Somewhat Agree
 Neutral
 Somewhat Disagree
 Strongly Disagree

2. *Addressing the geographic disparity in liver distribution should be a top priority for the OPTN.
 Strongly Agree
 Somewhat Agree
 Neutral
 Somewhat Disagree
 Strongly Disagree

3. *If the current distribution system were to change, how important are the following goals? (*Very important, Somewhat important, Neutral, Somewhat unimportant, Very unimportant*)
 - Reducing how much the severity of illness varies among all liver candidates at the time of transplant (for example, reducing variance of MELD/PELD scores at time of transplant)
 - Fewer deaths on the waitlist
 - Maximum transplant survival benefit
 - Optimal quality of life for liver recipients
 - Maximum number of patients transplanted

4. *In an effort to achieve these goals, I support creating larger distribution areas, as long as the proposal addressed issues such as cost, cold ischemia time, inappropriate discards, and other operational challenges.

- Strongly Agree
- Somewhat Agree
- Neutral
- Somewhat Disagree
- Strongly Disagree

5. *I would support developing revised policy that uses geographic allocation units (yes/no response for each):

- Fewer than 4 Districts
- 4 Districts
- 8 Districts
- Other (please describe in response to question 7)
- No change needed

6. *My level of concern about the following factors in increasing the size of distribution areas can be ranked as such: (Very concerned, Somewhat concerned, Neutral, Somewhat unconcerned, Not at all concerned):

Organ discards resulting from preliminary acceptances and subsequent non-use

- Very concerned
- Somewhat concerned
- Somewhat unconcerned
- Not at all concerned

Logistics involved in distant liver recoveries

- Very concerned
- Somewhat concerned
- Somewhat unconcerned
- Not at all concerned

Financial issues for OPOs and transplant centers

- Very concerned
- Somewhat concerned
- Somewhat unconcerned
- Not at all concerned

Implications of/for OPO performance

- Very concerned
- Somewhat concerned
- Somewhat unconcerned
- Not at all concerned

Incomplete communication between OPOs and transplant centers

- Very concerned
- Somewhat concerned
- Somewhat unconcerned
- Not at all concerned

Inadequate evidence basis for redrawing new distribution areas

- Very concerned
- Somewhat concerned
- Somewhat unconcerned
- Not at all concerned

Increasing the proportion of high MELD candidates transplanted, potentially reducing total life years possible for the candidate population as a whole

- Very concerned
- Somewhat concerned
- Somewhat unconcerned
- Not at all concerned

7. *The Liver Committee has analyzed the utility of several models to accomplish greater equity and less disparity in liver distribution. Please describe your support of any other potential solutions that should also be considered.

8. *What observations and lessons can the OPTN learn from previous changes to liver distribution policy to reduce variation in access for waitlisted candidates (For example, Share 35)?

9. *Please describe any other concerns or comments related to the concepts put forward in this concept document.

To help the committee understand the context for certain responses, please answer the following.

No individual or institution identifiers will be released to the Committee or public. Additionally, the Committee may be interested in contacting you for further discussion or presentation topics for the upcoming forum in September.

10. Name

11. Contact (phone number or email)

12. *State of residence (drop-down)

13. *Please identify your affiliation:

- Organ Procurement Organization
- Transplant Hospital
- Other OPTN member Organization
- Patient or patient family
- Other Public
- Prefer not to disclose

14. Institution (drop-down; asked only if they answer OPO, Transplant Hospital, or Other OPTN member organization above)